UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 23, 2020

MEMORANDUM:

SUBJECT: Review of the Request for a Public Health Exemption by the Texas Department of Agriculture for use of SurfaceWise™ 2 to Treat Orthopedic and Spine Clinics against SARS CoV-2

FROM: Stephen Tomasino, Ph.D., Senior Scientist
Microbiology Laboratory Branch
Biological and Economic Analysis Division (7503C)

THRU: Susan Lawrence, Branch Chief
Microbiology Laboratory Branch
Biological and Economic Analysis Division

TO: Tawanda Maignan, Section 18 Team Leader
Risk Integration, Minor Use, and Emergency Response Branch
Registration Division (7505C)

Purpose

BEAD's Microbiology Laboratory Branch (MLB) conducted a technical review of the Texas Department of Agriculture's (TDA) submission for a FIFRA Section 18 Public Health Emergency Exemptions (see Data Package Bean Sheet 20TX04; Decision #563909 dated June 17, 2020) for the use of 1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride (SurfaceWise™ 2) to reduce the spread of SARS CoV-2 on surfaces of two orthopedic sports and spine clinics (Total Orthopedic Sports and Spine Clinics) within the state of Texas. The supplied materials were reviewed for documented evidence, justification, and appropriateness to support a public health emergency and how, if approved, the use of SurfaceWise™ 2 could resolve the emergency and protect public health. The Antimicrobials Division in the Office of Pesticide Programs (OPP) will conduct a review of the efficacy data provided by the applicant.

Overview of the Request

The TDA has requested a FIFRA Section 18 Public Health Emergency Exemption for the use of 1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride (SurfaceWise™ 2) to treat surfaces contaminated or potentially contaminated with SARS CoV-2, the causal agent of COVID-19. The request is for treating high touch surfaces associated with two orthopedic sports and spine clinics within the state of Texas with SurfaceWise™ 2, in conjunction with current cleaning and disinfecting protocols, to aid in the control of SARS CoV-2.

- SurfaceWise™ 2 is not an EPA-registered product, and thus does not currently have EPA approval for sale or distribution under FIFRA as an antimicrobial product in the United States. The manufacturer of the Surface Wise™ 2 technology, Allied Bioscience, Inc., has been notified of the intent to deploy the technology by the TDA per the provisions described in the application. A draft label was provided for review (see proposed use below).
    - The active component of the SurfaceWise™ 2 formulation is a quaternary ammonium polymer with an organosilane backbone. TDA cites the presumed residual antimicrobial activity (i.e., several weeks) of the formulation on treated surfaces as the key characteristic in support of its use.
- The TDA's justification for a public health emergency exemption is based on the concept that surface contamination is a continuous process; i.e., after surfaces have been cleaned and disinfected with an EPA List N product (or products) they can be re-contaminated by patients and/or employees and serve as a potential source (i.e., reservoir of virus) of infection until they are cleaned and disinfected again. Furthermore, the applicant expressed the difficulty in shutting down and/or delaying use of orthopedic and spine clinic facilities as frequently as would be required to apply currently approved disinfectants, including hard-to-reach locations.
- According to the TDA, approved EPA registered disinfectants lack demonstrated residual efficacy for treating surfaces against SARS CoV-2 and are only effective at the time of application. If approved, the use of SurfaceWise™ 2 could provide additional residual protection against SARS CoV-2 for up to 7 days (per the amended label).
    - Thus, the main aspects of TDA's proposed public health emergency are: 1) even with rigorous cleaning and disinfection, EPA's List N products do not have residual activity to account for potential recontamination of surfaces, and 2) there are gaps in "protection" due to human error (i.e., missed areas for cleaning and disinfection.
- The alternatives identified by the applicant are disinfectants (over 480) approved by EPA (List N) for use against SARS CoV-2; however, the TDA cites the lack the residual activity of these products as the main concern to risk mitigation.
    - MLB recognizes List N disinfectants as alternatives. It should be noted that a limited number of EPA-registered antimicrobial products have demonstrated residual efficacy against bacteria; however, none are labeled for public health or viricidal claims, and all have relatively short residual times (e.g., 24 hours).

Proposed Use

The application of SurfaceWise™ 2 is intended to provide residual control of SARS CoV-2 for up to the proposed 7 days post application on hard non-porous surfaces. The technology would be used in conjunction with current routine cleaning and disinfecting protocols. SurfaceWise™ 2 is a ready to use formulation and would be applied with an electrostatic sprayer.

- Prior to application of SurfaceWise™ 2, the surface must be pre-cleaned/disinfected using an EPA-registered disinfecting/cleaner listed under List N: Disinfectants for use against SARS CoV-2, https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.
- SurfaceWise™ 2 would be applied immediately following pre-cleaning and disinfecting by approved List N disinfectant/cleaners using an electrostatic sprayer, setting the flowrate to 1 gallon of product/hour. Application at this rate is designed to cover approximately 3,200 ft^2/hr. Surfaces would be sprayed from a distance of 24 to 36 inches to the point of saturation being careful not to let the liquid start to drip; the product is applied to all hard non porous surfaces paying particular attention to the underside of surfaces.
- A sheen will be present on the surface following treatment. Following application, the treated surfaces are completely air-dried (approximately 10 minutes) prior to handling.
- The reapplication interval is subject to change based on additional data (presumably chemical stability, durability and efficacy data) and the written concurrence of both the Texas Department of Agriculture and the EPA.

Technical Review

1. The ongoing Covid-19 pandemic is an emergency in the United States. As part of the Federal Government's efforts to minimize risks to its citizens, the EPA released List N (Disinfectants for Use Against SARS CoV-2) and expedited the review of disinfectants for use against human coronavirus through the Emerging Viral Pathogens policy and PRIA process to provide additional products. As there are currently over 480 registered disinfectants on List N, the availability of disinfectants for treating surfaces is not considered an emergency at this time.
2. EPA-registered disinfectants with demonstrated residual activity are limited in number, not labeled for public health or viricidal claims, and the residual claims are relatively short (e.g., within 24-hours). Therefore, products with extended use periods, if proven effective, may be useful tools in addressing surface contamination for SARS CoV-2. There are currently no EPA-registered alternatives with demonstrated residual efficacy up to 7 days against SARS CoV-2.
3. Current Federal guidelines are in place to safely reopen and sustain businesses. Relevant guidelines include:
    a. Cleaning and Disinfecting Guidance was provided by EPA and CDC to assist businesses with safe and sustainable re-openings: https://www.cdc.gov/coronavirus/2019-ncov/community/pdf/Reopening_America_Guidance.pdf.

b. Interim Infection Prevention and Control Recommendations for Healthcare Personnel. Refer to https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
c. Federal guidance recommends timely cleaning and disinfection of high contact surfaces with EPA-registered List N disinfectant products for environmental infection control.

4. Based on the current submission, the immediate risk to public health of acquiring SARS CoV-2 from cleaned and disinfectant-treated surfaces in the orthopedic clinics following the potential redeposition of virus onto treated surfaces is unclear. However, in theory, products with demonstrated residue activity of several days or weeks in the disinfection toolbox may be useful under certain circumstances (e.g., high occupancy scenarios or high local infection rates) for risk mitigation in a wide variety of applications.
    a. TDA does not provide data to support the presumption that current stand-alone cleaning and disinfectant practices must be improved to further mitigate the risk to SARS CoV-2.
    b. TDA does not provide evidence/data that re-contamination of surfaces occurs at a rate and level where the use of current cleaning and disinfectant practices in a health care setting do not provide adequate mitigation of risk to SARS CoV-2.
    c. TDA did not identify the occurrence of a shortage or inability to procure List N products for treating the targeted surfaces. Furthermore, although the limitations to treat hard-to-reach places were noted, there are List N products applied via electrostatic sprayers. No specific issues (e.g., accessibility of the surface to be treated, complaints of product volatiles) or occurrence of material incompatibility were identified in the submission where SurfaceWise™ 2 would be deemed essential to the cleaning and disinfection of the facilities.
    d. If gaps of cleaning and disinfectant coverage are suspected in the field, then it may be appropriate to seek training for the applicators and increase on-site monitoring to ensure proper handling and application of List N products.

Recommendations

In the future, MLB recommends that applicants strengthen emergency use submissions through additional data collection and information gathering from the targeted use sites in the field. MLB recognizes that data collection and information gathering from the field is complex and technically challenging (e.g., many surface types and sampling limitations). Examples of additional information from targeted use sites that would strengthen submissions are provided below:

1. Evidence that the use of routine cleaning and disinfection practices in a healthcare setting is not feasible. If evidence is available from the two clinics which suggest List N disinfectants are ineffective in reducing exposure to human coronavirus, we encourage the applicant to provide the data to EPA.
2. Evidence of the recontamination rate and level on clinic surfaces to justify the use of a residual product in conjunction with routine cleaning and disinfection practices.
3. Evidence of shortages of appropriate List N disinfectants, issues of material compatibility, and accessibility to surfaces to be treated.

4. Efficacy data against human coronavirus that includes a coating durability component to support residual claims.
5. Evidence that the CDC's guidance for healthcare personnel is not adequate to effectively mitigate the risk of exposure to SARS CoV-2.
6. Evidence that the risk of acquiring SARS CoV-2 from potentially contaminated surfaces is the root cause for decline in the number of patients utilizing the services.

Conclusions

TDA's submission identifies the potential for an emergency situation at the two orthopedic clinics that may be addressed by the approved use of SurfaceWise™ 2. The risk-based data necessary to support the existence of a public health emergency at the two orthopedic clinics, or any other clinical setting, are difficult to ascertain. Unlike the companion Section 18 application for commercial aircraft and terminals (20TX05), employees in orthopedic clinics can control access and movement of patients and employees throughout their facilities, as well as monitoring and enforcing cleaning and disinfection practices between patients. We encourage TDA to consult the above referenced CDC guidelines for healthcare settings.

Regardless, MLB believes that the inclusion of a residual product such as SurfaceWise™ 2 may provide another option to the overall cleaning and disinfecting toolbox, and, in theory, the use of SurfaceWise™ 2 may further mitigate risk of human exposure to SARS CoV-2 when combined with the use of current List N products.

Please contact Stephen Tomasino at 410-305-2976 if you have any questions or comments regarding this review.

cc: Tajah Blackburn, Antimicrobials Division, OPP
Kristen Willis, Antimicrobials Division, OPP